

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the Application:

Listing of Claims

1. (Currently amended) An aqueous sprayable formulation for delivery of an immune response modifier to the nasal passage of a subject comprising:
an immune response modifier;
water; and
a hydrophilic viscosity enhancing agent;
with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;
wherein the formulation is a solution at room temperature, ~~and~~ has a viscosity of less than 100 cps at room temperature, and is contained in a nasal spray device.
2. (Currently amended) The aqueous formulation of claim 1 wherein the immune response modifier is a positively charged immune response modifier, or a pharmaceutically acceptable salt thereof.
3. (Previously presented) The aqueous formulation of claim 1 wherein the hydrophilic viscosity enhancing agent is negatively charged.
4. (Previously presented) The aqueous formulation of claim 1 wherein the hydrophilic viscosity enhancing agent is uncrosslinked.
5. (Previously presented) The aqueous formulation of claim 1 wherein the hydrophilic viscosity enhancing agent is selected from the group consisting of cellulose ethers, polysaccharide gums, acrylic acid polymers, and combinations thereof.

6. (Previously presented) The aqueous formulation of claim 1 wherein the hydrophilic viscosity enhancing agent comprises carboxylic acid groups and/or carboxylate groups.

7. (Previously presented) The aqueous formulation of claim 6 wherein the hydrophilic viscosity enhancing agent is selected from the group consisting of an acrylic acid polymer, carboxymethyl cellulose sodium, xanthan gum, and combinations thereof.

8-10. (Canceled)

11. (Currently amended) The aqueous formulation of claim 1 wherein the immune response modifier is a compound having a 2-aminopyridine fused to a five membered nitrogen-containing heterocyclic ring, or a pharmaceutically acceptable salt thereof.

12. (Currently amended) The aqueous formulation of claim 11 wherein the immune response modifier is selected from the group consisting of imidazoquinoline amines, tetrahydroimidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, imidazonaphthyridine amines, imidazotetrahydronaphthyridine amines, oxazoloquinoline amines, thiazoloquinoline amines, oxazolopyridine amines, thiazolopyridine amines, oxazolonaphthyridine amines, thiazolonaphthyridine amines, 1H-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, ~~or~~ tetrahydronaphthyridine amines, and pharmaceutically acceptable salts thereof, and combinations thereof.

13-14. (Canceled)

15. (Currently amended) The aqueous formulation of claim 12 wherein the immune response modifier is selected the group consisting of amide substituted imidazoquinoline amines, sulfonamide substituted imidazoquinoline amines, urea substituted imidazoquinoline amines, thioether substituted imidazoquinoline amines, 7-aryl substituted imidazoquinoline amines, 7-

heteroaryl substituted imidazoquinoline amines, sulfonamide substituted tetrahydroimidazoquinoline amines, and pharmaceutically acceptable salts thereof, and combinations thereof.

16. (Currently amended) The aqueous formulation of claim 15 wherein the immune response modifier is a sulfonamide substituted imidazoquinoline amine, or a pharmaceutically acceptable salt thereof.

17. (Currently amended) The aqueous formulation of claim 15 wherein the immune response modifier is selected from the group consisting of:

N¹-{4-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]butyl}-4-fluoro-1-benzenesulfonamide,

N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)propyl]morpholine-4-carboxamide,

N-{3-[4-amino-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2,2-dimethylpropyl}-N'-phenylurea,

N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,

2-butyl-1-[2-(propylsulfonyl)ethyl]-1*H*-imidazo[4,5-*c*]quinolin-4-amine,

N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-2-ethoxyacetamide,

N-{4-[4-amino-2-(cyclopropylmethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]butyl}methanesulfonamide,

N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-N'-cyclohexylurea,

N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}cyclohexanecarboxamide,

N-{2-[4-amino-2-(ethoxymethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,

N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-2,2-dimethylpropyl]methanesulfonamide,

N-[2-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-1,1-dimethylethyl]methanesulfonamide,

N-{2-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}methanesulfonamide,

1-[4-amino-7-(5-hydroxymethylpyridin-3-yl)-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,

1-[4-amino-7-(3-hydroxymethylphenyl)-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,

N-{3-[4-amino-1-(2-hydroxy-2-methylpropyl)-2-(methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]phenyl}methanesulfonamide,

{5-[4-amino-2-(2-methoxyethyl)-1-(2-methylpropyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]pyridin-3-yl}methanol,

1-[4-amino-2-(ethoxymethyl)-7-(pyridin-3-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,

1-{4-amino-2-(ethoxymethyl)-7-[5-(hydroxymethyl)pyridin-3-yl]-1*H*-imidazo[4,5-*c*]quinolin-1-yl}-2-methylpropan-2-ol,

N-(2-{4-amino-2-ethoxymethyl-7-[6-(methanesulfonylamino)hexyloxy]-1*H*-imidazo[4,5-*c*]quinolin-1-yl}-1,1-dimethylethyl)methanesulfonamide,

N-(6-{[4-amino-2-ethoxymethyl-1-(2-methanesulfonylamino-2-methylpropyl)-1*H*-imidazo[4,5-*c*]quinolin-7-yl]oxy}hexyl)acetamide,

N-[2-(4-amino-2-ethoxymethyl-1-propyl-1*H*-imidazo[4,5-*c*]quinolin-7-yloxy)ethyl]methanesulfonamide,

1-[4-amino-2-(ethoxymethyl)-7-(1*H*-pyrazol-4-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2-methylpropan-2-ol,

3-[4-amino-2-(ethoxymethyl)-7-(pyridin-3-yl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]propane-1,2-diol,

and pharmaceutically acceptable salts thereof, and combinations thereof.

18. (Currently amended) The aqueous formulation of claim 17 wherein the immune response modifier is selected from the group consisting of:

N-[3-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)propyl]morpholine-4-carboxamide,
N-{3-[4-amino-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-2,2-dimethylpropyl}-
N'-phenylurea,
N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-
dimethylethyl}methanesulfonamide,
2-butyl-1-[2-(propylsulfonyl)ethyl]-1*H*-imidazo[4,5-*c*]quinolin-4-amine,
N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-2-
ethoxyacetamide,
N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-dimethylethyl}-N'-
cyclohexylurea,
N-{2-[4-amino-2-(ethoxymethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-
dimethylethyl}methanesulfonamide,
N-[2-(4-amino-2-butyl-1*H*-imidazo[4,5-*c*]quinolin-1-yl)-1,1-
dimethylethyl]methanesulfonamide,
N-{2-[4-amino-2-(2-methoxyethyl)-6,7,8,9-tetrahydro-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-
dimethylethyl}methanesulfonamide,
1-{4-amino-2-(ethoxymethyl)-7-[5-(hydroxymethyl)pyridin-3-yl]-1*H*-imidazo[4,5-
c]quinolin-1-yl}-2-methylpropan-2-ol,
N-(6-{[4-amino-2-ethoxymethyl-1-(2-methanesulfonylamino-2-methylpropyl)-1*H*-
imidazo[4,5-*c*]quinolin-7-yl]oxy}hexyl)acetamide,
and pharmaceutically acceptable salts thereof, and combinations thereof.

19. (Currently amended) The aqueous formulation of claim 18 wherein the immune response modifier is N-{2-[4-amino-2-(ethoxymethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]-1,1-
dimethylethyl}methanesulfonamide, or a pharmaceutically acceptable salt thereof.

20. (Original) The aqueous formulation of claim 11 wherein the immune response modifier is a salt of an acid selected from the group consisting of a carboxylic acid, a halo acid, sulfuric acid, phosphoric acid, dicarboxylic acid, tricarboxylic acid, and combinations thereof.

21. (Original) The aqueous formulation of claim 20 wherein the salt of the immune response modifier is a salt of an acid selected from the group consisting of hydrobromic acid, hydrochloric acid, lactic acid, glutamic acid, gluconic acid, tartaric acid, succinic acid and combinations thereof.

22-34. (Canceled)

35. (Currently amended) An aqueous sprayable formulation for delivery of an immune response modifier to the nasal passage of a subject comprising:

an immune response modifier selected from the group consisting of imidazoquinoline amines, tetrahydroimidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, imidazonaphthyridine amines, imidazotetrahydronaphthyridine amines, oxazoloquinoline amines, thiazoloquinoline amines, oxazolopyridine amines, thiazolopyridine amines, oxazolonaphthyridine amines, thiazolonaphthyridine amines, 1H-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, ~~or~~ tetrahydronaphthyridine amines, and pharmaceutically acceptable salts thereof, and combinations thereof;

water; and

a hydrophilic viscosity enhancing agent selected from the group consisting of cellulose ethers, polysaccharide gums, acrylic acid polymers, and combinations thereof;

with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature, ~~and~~ and has a viscosity of less than 100 cps at room temperature, and is contained in a nasal spray device.

36. (Withdrawn) A method for delivering an immune response modifier to a nasal passage of a subject, the method comprising:

selecting a formulation comprising:

an immune response modifier;

water; and

a hydrophilic viscosity enhancing agent;

with the proviso that the hydrophilic viscosity enhancing agent is not covalently bonded to the immune response modifier;

wherein the formulation is a solution at room temperature and has a viscosity of less than 100 cps at room temperature; and applying the selected formulation into a nasal passage or a subject.

37. (Withdrawn) A method of treating and/or preventing allergic rhinitis, the method comprising applying the formulation of claim 1 into a nasal passage or a subject.

38. (Canceled)

39. (Withdrawn) A method of treating and/or preventing a viral infection, the method comprising applying the formulation of claim 1 into a nasal passage of a subject.

40. (Canceled)

41. (Withdrawn) A method of treating and/or preventing sinusitis, the method comprising applying the formulation of claim 1 into a nasal passage of a subject.

42. (Canceled)

43. (Withdrawn) A method of treating and/or preventing asthma, the method comprising applying the formulation of claim 1 into the respiratory tract of a subject.

44. (Canceled)

45. (Withdrawn) A method of desensitizing a subject to an antigen comprising:
administering to the subject an IRM compound in the formulation of claim 1, after the subject has been sensitized to the antigen, in an amount effective to desensitize the subject to the antigen.

46 - 48. (Canceled)

49. (Previously presented) The aqueous formulation of claim 1 wherein the hydrophilic viscosity enhancing agent is selected from the group consisting of cellulose ethers, polysaccharide gums, acrylic acid polymers, and combinations thereof; and wherein the hydrophilic viscosity enhancing agent further comprises carboxylic acid groups and/or carboxylate groups.